anticholinergic properties. This argument is accompanied by Janssen's complementary argument that those of ordinary skill in the art would not have been motivated to modify the structure of Pirenperone, even though Pirenperone was both a potent dopamine antagonist and a potent serotonin antagonist, because only a portion of those of ordinary skill in the art considered the combination of dopamine and serotonin antagonism to be important in an antipsychotic. *See* FF/CL § IV.B.

This position is legally and factually flawed. First, the existence of alternative theories in the art does not then render all things made under those theories patentable. Further, Janssen is once again faced with the problem of arguing against itself. Janssen does not dispute that Janssen did not follow the anticholinergic theory, and Janssen does not dispute that Janssen believed that an antipsychotic in the early 1980s should have both dopamine antagonism and serotonin antagonism—and that Janssen itself taught that position in the prior art. *Id.*

C. Janssen's Position That There Were Other Compounds That One of Skill in The Art Might Also Have Chosen to Modify is Legally Irrelevant

Janssen further argues that, even if one of ordinary skill in the art were motivated to consider Pirenperone when developing an antipsychotic, there were other compounds that one of ordinary skill in the art might also have chosen to

modify. This argument is legally irrelevant. There is no legal principal that holds that having multiple means to solve a problem renders all solutions patentable. Indeed, the law is to the contrary. Obviousness has been found even when inventors have selected certain compounds from among thousands of compounds. *See, e.g. Merck & Co., Inc. v. Biocraft Labs, Inc.,* 874 F.2d 804, 807 (Fed. Cir. 1989). *See* FF/CL § IV.C.

IV. JANSSEN HAS FAILED TO ESTABLISH A NEXUS BETWEEN THE ALLEGED "SECONDARY CONSIDERATIONS" OF NONOBVIOUSNESS AND THE '663 PATENT CLAIMS

Janssen contends that the secondary considerations of nonobviousness relative to Risperdal® support a finding that the claims are nonobvious. To prevail in this argument, however, Janssen must demonstrate that the secondary considerations are commensurate with the scope of the claims. Janssen's proofs failed in this regard, as they addressed only Risperidone and ignored Compound 11. *See In re Peterson*, 315 F.3d 1325, 1330-31 (Fed. Cir. 2003). (When a claim is directed to a range "about 1 to 3 percent," unexpected results related to one point within that range does not overcome a *prima facie* showing of obviousness). Indeed, it is uncontested that Compound 11 was never commercialized, and that there are no secondary considerations of nonobviousness associated with this compound. *See* FF/CL § V.

In the context of genus claims covering numerous species, merely establishing that there are secondary considerations of nonobviousness for one compound covered by a claim is inadequate proof that these considerations are relevant to another compound covered by the claim. *See In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978); *In re Tiffin*, 443 F.2d 394, 395 (C.C.P.A. 1971), *amended by* 448 F.2d 791, 791-92 (C.C.P.A. 1971) (evidence with respect to "cups" was not commensurate with the scope of claims reciting "containers"); *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (evidence with respect to one species was insufficient when challenged claim covered multiple species). *See also In re Lindner*, 457 F.2d 506, 508 (C.C.P.A. 1972). *Id.*

Janssen attempted to argue that Risperidone and Compound 11 are really the same invention, but this attempt was factually unsupported. The structures of Risperidone and Compound 11 are different. Moreover, because of this difference, it is unlikely that Compound 11 would behave in the body in the same manner as Risperidone, the latter forming a highly active metabolite at the very part of its structure that is different from Compound 11. These facts have not been refuted. *Id.*

V. INEQUITABLE CONDUCT

Central to Mylan's charge of inequitable conduct is Janssen's withholding of material information (the potent dopamine antagonism of Pirenperone) from the

Patent Examiner during the prosecution of the '663 patent in violation of a duty of disclosure imposed on all patent applicants. Janssen now *admits* that while it knew this information, it did not disclose it to the Patent Examiner—information that was highly material to the examination of Janssen's '663 patent. This withholding is just one example of the deceptive acts perpetrated on the USPTO by Janssen during the prosecution of the '663 patent, this pattern serving to establish that Janssen acted with an intent to deceive the USPTO. *See* FF/CL § VI.

A. The Law Pertaining to Inequitable Conduct

Patent applicants (namely, the inventor), the prosecuting attorney or agent, and anyone associated with the inventor or the assignee who is substantively involved in the preparation or prosecution of the application, owe a "duty of candor and good faith" to the USPTO. 37 C.F.R. § 1.56(a) (1984); *see also Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). A breach of this duty constitutes inequitable conduct. This breach can arise from a failure to disclose information material to patentability, coupled with an intent to deceive or mislead the USPTO. *See Molins*, 48 F.3d at 1178. *See* FF/CL § VI.A.1.-3.

Once materiality and intent have been established, the district court must weigh these factors in light of all of the circumstances to determine whether a finding that inequitable conduct occurred is warranted. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003) (citing *Purdue*

Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). When balanced against high materiality, the showing of intent can be proportionally less. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003) (citation omitted). *See* FF/CL § VI.A.4.

Materiality and intent are questions of fact. *See Pharmacia Corp. v. Par Pharms., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005). Inequitable conduct must be established by clear and convincing evidence. *See Molins*, 48 F.3d at 1178.

Under the regulations in place during prosecution of the '663 patent, "information is material where there is a substantial likelihood that a reasonable patent examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a) (1984). This is often referred to as "the Rule 56 standard." *See* FF/CL § VI.A.2.

Materiality does not require that any withheld information, if it had been provided, would have resulted in a rejection of the patent claims by the Patent Examiner. On the contrary, information can be "material" even if a Patent Examiner (or the Court today) would find the claimed invention to be patentable after considering such information. *See Digital Control Inc. v. Charles Machine Works,* 437 F.3d 1309, 1313-19 (Fed. Cir. 2006); *Bristol-Myers Squibb Co.,* 326 F.3d at 1237-38 (withheld reference was material notwithstanding patent examiner's determination that it did not render the invention unpatentable); *Merck & Co. v. Danbury Pharm., Inc.*, 873 F.2d 1418, 1420-22 (Fed. Cir. 1989) (withheld

prior art and information was material even though it did not render the patent claims invalid). *Id.*

Intent is usually proven by inference, not direct evidence. *See Merck & Co.*, 873 F.2d at 1422 ("Intent need not, and rarely can, be proven by direct evidence."). *See* FF/CL § VI.A.3.

Intent to deceive is often inferred where, as here in the case of Pirenperone's dopamine antagonism, applicants fail to disclose material information that the USPTO cannot obtain on its own. *See, e.g., Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996) (inferring intent to deceive in part because the USPTO had no way of otherwise obtaining the omitted information). *See* FF/CL § VI.A.3.

Indeed, in the absence of a credible explanation, intent to deceive is generally inferred from the fact and circumstances surrounding a knowing failure to disclose material information. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005). *See* FF/CL § VI.A.3.

A patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish subjective good faith sufficient to prevent the drawing of an inference of intent to mislead. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997). *See* FF/CL § VI.A.3.

A mere denial of intent to mislead the USPTO will not rebut an inference of an intent to mislead where the withheld information is material and the patentee knew or should have known of that materiality. *See Semiconductor Energy Lab. Co., Ltd. v. Samsung Elects. Co., Ltd.*, 204 F.3d 1368, 1375-76 (Fed. Cir. 2000). *See* FF/CL § VI.A.3.

B. Pirenperone's Undisclosed Activity as a Dopamine Antagonist was Highly Material

Central to the materiality aspect of Defendants' inequitable conduct case is that the dopamine antagonism of Pirenperone was withheld from the Patent Examiner by Janssen during the prosecution of the '663 patent. That this information was "material" under the Rule 56 standard should not be in dispute because Janssen told the Patent Examiner that information concerning dopamine antagonism was important in deciding whether to allow the application to issue as a patent. *See* FF/CL § VI.B.1.-3.

It was Janssen who, during prosecution, told the Patent Examiner that, unless it was demonstrated that the prior art compounds were dopamine antagonists, they were not relevant to the patentability of the claims of the '663 patent. Janssen also told the Patent Examiner that prior art compounds possessing anti-serotonin activity were not relevant to patentability. Janssen cannot now argue to the contrary—that dopamine antagonism is not information that would

have been important in the Patent Examiner's decision to allow the '663 patent application to issue as a patent under the Rule 56 standard. *Id.*

C. Intent to Deceive is Present

1. General Background

Janssen is expected to argue that no one person at Janssen acted with an intent to deceive, and that Defendants have no evidence of any such deceptive intent. As is well appreciated, intent is often proven only through inferences based upon established facts. Defendants established a plethora of facts upon which such intent may and should be inferred. *See* FF/CL § VI.E.1.-3. During prosecution, Janssen:

1. Submitted a single prior art reference relating to Pirenperone, the '870 patent (prosecuted by Dr. Dellenbaugh, with Mr. Kennis as an inventor), with a description in the IDS that it "describe[s] intermediates and processes useful to prepare the claimed compounds." The '870 patent only discloses Pirenperone's activity as a serotonin antagonist, and as Janssen admits discloses nothing concerning its potent dopamine antagonism.

2. Told the Patent Examiner that prior art patents that disclosed compounds which only possessed serotonin antagonism were *not* relevant from the standpoint of possessing anti-psychotic activity.

3. Told the Patent Examiner that only prior art compounds that possess dopamine antagonism were relevant to the patentability of compounds having anti-psychotic activity.

4. Admittedly knew that Pirenperone was a dopamine antagonist, but did not tell the Patent Examiner that Pirenperone was a dopamine antagonist.

5. Published at least four prior art papers (three of which were co-authored by Dr. Paul Janssen and one co-authored with Dr. Awouters) touting the effectiveness of Pirenperone as a dopamine antagonist, but disclosed none to the Patent Examiner.

6. Performed clinical trials of Pirenperone in scores of patients, the results of which were published in the prior art, but disclosed nothing to the Patent Examiner regarding this extensive clinical testing.

7. Was aware of the fact that Pirenperone suffered from a short half-life in the body and knew that such information was part of the prior art, yet disclosed none of this information to the Patent Examiner.

8. During prosecution, submitted the "Awouters Declaration" establishing that a prior art compound, Ketanserin, was not an effective dopamine antagonist. Yet, at the time of drafting that Declaration, Dr. Awouters had on his desk a Janssen research report that contained side-by-side data concerning the properties of Ketanserin, Pirenperone and

Risperidone as dopamine antagonists, establishing that Pirenperone was at least as good as Risperidone as a dopamine antagonist.

Janssen admits that within the Janssen organization, Dr. Janssen himself and Dr. Awouters knew that Pirenperone was a potent dopamine antagonist, and that discussions between work undertaken by Dr. Awouter's research group and Mr. Kennis' research group concerning Janssen compounds were commonplace. Janssen also cannot deny that Dr. Dellenbaugh told the Patent Examiner that a compound must have dopamine antagonism for it to be relevant as prior art. *Id.*

Further support for Janssen's intent to mislead arises from Janssen's withholding of dopamine antagonism (ATN) data for a compound described and claimed in the '663 patent as Compound 4. This data, located in Janssen's '663 patent file, demonstrates that this claimed compound possesses virtually no dopamine antagonism (*i.e.*, no antipsychotic activity). Instead of being submitted to the USPTO as part of the application, or when faced with a lack of utility rejection during prosecution as part of its duty of disclosure of *all* information material to patentability (*i.e.*, both favorable and, as here, unfavorable), Janssen instead withheld this data, and at trial offered no explanation as to why data which demonstrated that a claimed compound had little, if any, dopamine antagonism was not brought to the attention of the USPTO. *Id.*

2. Dr. Dellenbaugh

As part of his duties, Dr. Dellenbaugh was responsible for the prosecution of the '663 patent, including the submission of an Information Disclosure Statement ("IDS"). Despite affirmatively representing to the USPTO that after consultation with the inventors he was identifying the closest prior art to the '663 patent, it was discovered at trial that he did no such thing, and confirmed that his statement to the USPTO was false. Dr. Dellenbaugh testified that he did not speak with the inventors (including Mr. Kennis) about the prior art as he had told USPTO, but instead relied upon information provided to him by an inexperienced Janssen patent agent to gather this highly material information. *See* FF/CL § VI.E.1.

Later in his testimony, however, Dr. Dellenbaugh stated that he had no actual recollection as to the source of the information in the IDS, although it was revealed that Dr. Dellenbaugh possessed a compilation of Janssen compounds, their structures and properties that had been prepared for him by the Janssen patent department. *Id.*

Moreover, the description of the Pirenperone patent in the IDS as disclosing nothing more than intermediates and processes useful in preparing the claimed compounds was misleading. This conveyed the impression to the Patent Examiner that Pirenperone was not relevant at all to the patentability of the '663 claims. *Id.*

When it came to the issue of the specific Declaration by Dr. Awouters, Dr. Dellenbaugh testified that he believed that he requested that Declaration. Dr.

Dellenbaugh further testified that he believed that the Declaration was prepared in Belgium. But the preparation of the Declaration certainly was not done in a vacuum. Dr. Dellenbaugh testified that it was his practice to keep the Janssen patent department informed of what was going on in U.S. prosecution of the Janssen patent applications.

REDACTED

So we have Dr. Dellenbaugh, fully cognizant of the importance of the undisclosed dopamine data, with his compilation of Janssen compounds with associated structures and properties. We have Dr. Awouters and Dr. Janssen in Belgium fully aware of the dopamine data related to Pirenperone (who communicated regularly with Mr. Kennis, an inventor of the '663 patent). We have Dr. Dellenbaugh, who traveled to Belgium frequently to meet with the Janssen patent department, and who prosecuted both the '663 patent and the Pirenperone patent. We have Mr. Kennis as a named inventor on both the '663 and Pirenperone patents. **REDACTED**

And all Dr. Dellenbaugh knew about Pirenperone was that it was a serotonin antagonist? Hardly. Intent to deceive may and should be inferred under the circumstances.

3. Dr. Paul Janssen

Janssen argues that Dr. Paul Janssen had "slender involvement in the patent." This is contrary to the deposition testimony of

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As a general business practice, patent applications in the United States, as well as continuations thereof, were filed only with the approval of Dr. Janssen. Contrary to the testimony of Mr. Kennis, Plaintiff Janssen would now have us believe that such decisions to file were made by Dr. Janssen in a vacuum, with no knowledge or discussion regarding the contents or merits of any such patent application. Moreover, Dr. Paul Janssen was a co-author on numerous prior art articles that touted the dopamine antagonist properties of Pirenperone. Clearly, Dr. Janssen knew that such information was useful in predicting Pirenperone's activity as an antipsychotic. *Id.*

Further, Dr. Janssen was a co-author with Dr. Awouters of an improperly withheld (during discovery) internal Janssen research report concerning the comparative dopamine antagonist properties of Pirenperone, Ketanserin (the Janssen compound focused upon by the Patent Examiner through Janssen's misdirection) and Risperidone. Dr. Paul Janssen was not merely a "high-level executive," he was much more; he was intimately involved in the filing of the application that led to the '663 patent, and clearly had the critical knowledge

regarding Pirenperone's dopamine antagonist properties. *Id.* Intent to deceive should be inferred.

4. Dr. Awouters

Dr. Awouters executed a declaration during the prosecution of the '663 patent which compared certain properties, including dopamine antagonism, of Ketanserin and Risperidone. This declaration did not include any mention of Pirenperone or its potent dopamine antagonism, or of any other prior art compound. *See* FF/CL § VI.E.3

Janssen has asserted that all the record reveals is that Dr. Awouters was asked by Janssen to provide information about a particular compound, Ketanserin. That statement is false. There is no "record" that reveals anything directly about what Dr. Awouters was asked to provide (or not provide) in his Declaration. Janssen's portrayal of Dr. Awouters' involvement is merely Janssen's best hope to obscure Dr. Awouters' participation in the cover-up that forms a basis for its inequitable conduct. *Id.*

Janssen's position is that there is no evidence that Dr. Awouters did anything more than read the '663 patent and prepare a declaration discussing the test results of Ketanserin. This allegation strains credulity; asking the Court to assume that one day Dr. Awouters decided that he should write-up a declaration about Ketanserin, having no understanding concerning the underlying reasons for the

Declaration, is patently absurd. The record is replete with facts regarding meetings between the pharmacology group of which Dr. Awouters was a member, and the chemical synthesis group of which Mr. Kennis was a member. *Id.*

REDACTED

Janssen's position apparently is that Dr. Awouters was in a "box," completely isolated from any knowledge concerning the '663 patent at the time he was preparing his Declaration. This is simply not believable. There is ample factual basis to conclude that Dr. Awouters knew the context of the information provided in his declaration, and Janssen has provided nothing more than speculation in response.

In fact, Janssen's actions during fact discovery which precluded the Defendants from deposing or even contacting Dr. Awouters serve only to strengthen the factual and inferential underpinnings of Defendants' inequitable conduct defense. *Id.* These actions, and a request for relief, are set forth in a separate motion.

5. An Inference of Intent is Appropriate Under the Circumstances

It is appropriate to draw an inference of deceptive intent in the present case because the properties of the prior art compounds were in issue during prosecution, *e.g.*,

dopamine antagonism, and the USPTO does not have the ability to conduct its own testing to determine whether any prior art compounds possess this property. Here, the USPTO was completely dependent upon the Janssen '663 patent prosecution team's representations regarding the properties of prior art compounds and disclosures of information material thereto concerning a compound's dopamine antagonism. As Janssen has admitted, however, the Patent Examiner was never given a fair opportunity to examine the '663 patent claims, because Janssen withheld dopamine antagonism on its own compound (Pirenperone). Intent to deceive is often inferred where, as here, applicants fail to disclose material information that the USPTO cannot obtain on its own. *See, e.g., Refac Int'l, Ltd.,* 81 F.3d at 1582 (inferring intent to deceive in part because the USPTO had no way of otherwise obtaining the omitted information). *See* FF/CL § VI.E.4.

Janssen has not, and indeed cannot, rebut the inference—it cannot offer a credible explanation for its nondisclosure of this highly relevant information. Although Janssen's counsel claimed to represent Dr. Awouters, counsel refused to make him available for deposition (thereby precluding Defendants from obtaining discovery); Dr. Janssen is deceased;

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and Dr. Dellenbaugh either failed to recall anything concerning the prosecution of the '663 patent during his deposition or accepted the advice of counsel and refused to testify

on the basis that to do so would violate the attorney-client privilege. The Federal Circuit recently held in *Bruno* that "in the absence of a credible explanation, intent to deceive *is generally inferred* from the facts and circumstances surrounding a knowing failure to disclose material information." *See Bruno,* 394 F.3d at 1354 (emphasis added). There are compelling reasons to infer an intent to deceive in the present case. *See* FF/CL § VI.E.4.

(a) Janssen's Reliance on "Circular Reasoning" in an Attempt to Rebut Intent Has Been Rejected by the Federal Circuit

Janssen argues that those involved in the prosecution of the '663 patent either: (1) did not know that Pirenperone was a potent dopamine antagonist or, (2) if they did know, they did not appreciate the significance of this information to the prosecution of the '663 patent. In either case, Janssen concludes that under these circumstances, no one could have had an intent to deceive the USPTO. *See* FF/CL § VI.E.4.

The Federal Circuit has routinely dismissed this type of "circular reasoning," most recently in the *Novo* case. *See Novo Nordisk Pharmaceuticals Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005). In *Novo*, the patentee (Novo) argued during prosecution that an example in an earlier filed PCT application permitted it to antedate a certain prior art reference, thereby rendering the application patentable. What Novo did not tell the USPTO, however, was that

the example in the PCT application was prophetic, *i.e.*, that the experiment described in the example had never been successfully performed. *Id.* at 1359-60. Novo argued on appeal that the district court never made a finding that anyone at Novo had *actual knowledge* that the example was prophetic, or appreciated the significance of this to the prosecution of the application. Novo asked the Federal Circuit to hold, on the one hand, that the failure of the inventors to disclose the truth about the example to Novo's attorneys absolves them of their duty to disclose this information to the USPTO, because without their attorney's consultation, they could not have known that this information was material. At the same time, Novo asked the Federal Circuit to hold that its counsel's failure to disclose the truth about the example to the USPTO is excused because the inventors failed to fully inform them of the details surrounding the example. *Id.* at 1361-62. *See* FF/CL § VI.E.4.

The Federal Circuit, noting as it has done "in similar situations in the past," rejected the "circular logic" of this request. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001) ("We refuse to pursue the circular logic of Brasseler's request and decline to carve out an exception to the inequitable conduct law to shield those guilty of inequitable conduct from responsibility for their actions."); *see also Molins*, 48 F.3d at 1178 (stating that the knowledge and actions of an applicant's representatives are chargeable to the applicant). Accordingly, the Federal Circuit held that the district court correctly

concluded that Novo, *i.e.*, not any particular individual but the corporate entity, knew or should have known that the USPTO would have considered the information relating to the example important in evaluating whether reliance on the PCT application was legally proper. Thus, the Federal Circuit found that the inference of deceptive intent by the district court was not clearly erroneous. *Novo Nordisk Pharmaceuticals Inc.*, 424 F.3d at 1362. *See* FF/CL § VI.E.4.

(b) Janssen's "Cultivated Ignorance" Is No Defense to Inequitable Conduct

Janssen's explanation of how no one at Janssen appreciated the significance of the highly material information it admittedly withheld from the USPTO smacks of cultivated ignorance. This type of defensive strategy, however, was rejected long ago by the Federal Circuit. A patent applicant may not "cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art." *FMC Corp. v. Hennessy Industries, Inc.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987). Once an attorney, or an applicant, has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose. *Brasseler, U.S.A. I, L.P.*, 267 F.3d at 1383. *See* FF/CL § VI.E.4.

Further, intent to deceive need not be manifested through an individual. A corporation, through its officers, employees and/or agents, also can manifest intent

to deceive the USPTO by conduct which amounts to a "studied ignorance" of the facts and which exhibits a "reckless indifference" to the truth. Particularly, when there is a complete absence of evidence of good faith. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.,* 746 F. Supp. 1413, 1414-15 (N.D. Cal. 1990). *See* FF/CL § VI.E.4.

In short, a company may not conduct sweeping studies of an invention, compartmentalize the results in separate divisions, and then submit only discrete portions of those results to the USPTO in support of specific claims while claiming ignorance of other, potentially highly material information, because that information was in a different compartment. *Ranbaxy Laboratories Ltd. v. Abbott Laboratories,* No. 04C8078, 05C1490, 2005 WL 3050608, *8 (N.D. Ill., Nov 10, 2005). *See* FF/CL § VI.E.4.

Even if an organization had a policy of never disclosing certain information (*e.g.*, Office Actions in copending prosecutions), that policy cannot erase the inference of deceptive intent that arises from withholding information an attorney knew or should have known could be material to patentability. Attorneys cannot insulate themselves against charges of inequitable conduct by instituting policies that prevent them from complying with the law. Under Federal Circuit case law, "studied ignorance" supports, rather than defeats, an inference of deceptive intent. *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, No.

CIVS022669FCDKJM, 2006 WL 1652518, *21 (E.D. Cal., June 13, 2006). *See* FF/CL § VI.E.4.

Under the foregoing standard, Janssen's explanations of the actions (or inaction) of at least Dr. Dellenbaugh, as well as others associated with the preparation and prosecution of the '663 patent, fall far short of a satisfactory explanation for its admitted withholding of highly material information. What is clear, however, is that there existed at Janssen a pattern of withholding highly material information from, and providing misleading information (by Dr. Dellenbaugh and others) to, the USPTO in an effort to prevent the Patent Examiner from having a complete view of the prior art. Moreover, there was reliance on inexperienced members of the Janssen patent department on issues of substantive U.S. patent law. In prosecuting the '663 patent in this manner, Janssen could be secure in the thought that the patent should issue while at the same time being able to fend off an enforceability challenge based on an alleged lack of complete understanding of the issues by relevant Janssen personnel.

Janssen's conduct should not be condoned—these facts should be used as a basis of inferring intent on the part of the foregoing individuals and, indeed, on the part of Janssen itself.

VI. THE '663 PATENT SHOULD BE FOUND UNENFORCEABLE

Defendants established at trial that, *inter alia*, the information regarding the dopamine antagonism of Pirenperone admittedly withheld from the USPTO by Janssen was highly material to the patentability of the '663 patent claims, and that the actions of each of Dr. Dellenbaugh, Dr. Awouters, Dr. Janssen and others at Janssen substantively involved in the preparation and prosecution of the '663 patent was intended to deceive the USPTO. A balance of materiality and intent indicates that the '663 patent was procured via inequitable conduct. Accordingly, the '663 patent should be found unenforceable. *See* FF/CL §§ VI.F.-G.

VII. EXCEPTIONAL CASE

A finding of inequitable conduct can provide a basis for an award of attorneys' fees to Defendants under 35 U.S.C. § 285. *See Brasseler,* 267 F.3d at 1386. It is therefore requested that the Court award Defendants their attorneys' fees. *See* FF/CL § VII.

VIII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court find all claims of the '663 patent invalid as obvious, that the '663 patent is unenforceable due to inequitable conduct on the part of Janssen during the prosecution of the '663 patent, and award Defendants their attorneys' fees and other relief as set forth in their answers and counterclaims.

Respectfully submitted,

SAIBER, SCHLESINGER, SATZ & GOLDSTEIN, LLC

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